



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** The Development of Gene Expression Signatures of Neoplasm Responsiveness to mTOR and HDAC Inhibitor Combination Therapy

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Empire Genomics LLC of an exclusive patent license to practice the inventions embodied in US Provisional Patent Application 61/558,402 entitled, “Gene Expression Signatures of Neoplasm Responsiveness to Therapy” [HHS Ref. E-013-2012/0-US-01], and all continuing applications and foreign counterparts. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to:

the use of the licensed patent rights limited to an FDA-cleared or an FDA-approved *in vitro* diagnostic test kit for human use and predictive of the

therapeutic benefit of combination therapy comprising an HDAC inhibitor and an mTOR inhibitor in the treatment of multiple myeloma, breast cancer, melanoma, lymphoma, and prostate cancer.

**DATE:** Only written comments or applications for a license, or both, which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Patrick P. McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; E-mail: [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** This invention concerns the discovery of gene expression signatures indicative of tumors that are sensitive to combination therapy comprising mTOR and HDAC inhibitors. Broadly applicable to several cancer subtypes, the detection of such signatures in a tumor could be used to identify a patient as a potential candidate for mTOR and HDAC inhibitor combination therapy.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless the NIH receives, within fifteen (15) days from the date of this published notice, written evidence and argument that establishes that the grant of the

license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

December 31, 2012  
Date

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Richard U. Rodriguez  
Director  
Division of Technology Development & Transfer  
Office of Technology Transfer  
National Institutes of Health

[FR Doc. 2012-31743 Filed 01/03/2013 at 8:45 am; Publication Date: 01/04/2013]